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To: Dr. R. B. Seligman

pate: May 15, 1981

From:

T. S. Osdene

Subject: .

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B.A.T. Guidance Panels on Additives and Materials (Your Memo, May 14, 1981)

During our recent discussions in London with Dr. Geoff Felton and Dr. Lionel Blackman, we were told that B.A.T. has two advisory panels. One of these is the Additives Guidance Panel (AGP) which deals with the deliberate addition of substances to the product. The other is the Material Guidance Panel (MGP) which deals with materials used on or in equipment or in the vicinity of equipment and which could inadvertently contaminate the product. In addition, this panel is also concerned with the British equivalent of OSHA. Both of these panels act as a part of the head office of B.A.T., that is, as a B.A.T. corporate function.

The AGP has the following functions:

- 1. To discuss the toxic aspects of additives in light of published information from the technical press or other sources such as governmental laws and ordinances.
- To obtain scientific opinions on each additive under question.
- To make recommendations whether or not to use such additives in such proportions as it considers should be non-injurious or to their <u>non-use</u>.
- 4. To make recommendations, when required, as to the kind and extent of any further testing that may be considered necessary and desirable.
- 5. To give advice, as required, on any aspects of additives.

It should be noted that this panel is <u>purely advisory</u> in nature and as part of their charge from the legal advisors of B.A.T. they exercise great care in their pronouncements. Thus, they will never make a claim of safety or of danger for an additive or suspect material.

Next it should be noted that the panel will <u>only respond</u> to a specific question which is posed to them. Thus, the request for a testing advice, etc., must come from one of the operating companies or divisions. The disseminations of findings of the panel to interested parties are the

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written minutes which are circulated. (They are the only written records kept.) These records only reflect a decision but do <u>not</u> give any reasoning for the decision. Thus, the total record only represents answers to questions as they have been asked. For example, the requestor must request a specific level in the product (eg 50ppm), the answer of the panel will be given in terms of the finished product only. Thus, if theoretically, one had additives A plus B plus C, the panel might answer that the toxic limit for the total may be 50ppm or that the request is acceptable. It must once again be emphasized that they will only answer specific questions they are asked.

The panel normally consists of three or four scientists, one of which acts as a secretary and two of which have experience in acting as toxicologists. In the instance of the specific panel, Dr. Felton himself is the fourth scientific member and is the chairman. In addition, one lawyer is an ex officio member of the group. It also includes a representative from the Leaf Department whose expertise is involved in recommending blends and flavorants for new products. One representative from Production, which in the B.A.T. content is the usual route for distributing technical information, and one person from Purchasing who keeps an eye on what is ordered and purchased.

All these members have fairly high level positions within the company. In general, both of these panels work as an adjunct to the head office, particularly in the case of the MGP, since much of the machinery and other materials are purchased centrally.

The minutes of the additives panel are distributed to the major research centers throughout the B.A.T. empire. It should, however, be noted that B&W-USA, B.A.T.-Germany as well as B.A.T.-Australia do their own evaluation and Felton is not sure whether they have a system as formalized as the one described above. The panel normally meets three times a year. They have a preliminary technical meeting and will give a reply in writing in the form of the minutes at the time of the next meeting. They make recommendations for further biological testing, and these will often be based on advice of outside consultants. It should be noted that if outside consultants are used, their advice becomes gospel and cannot be ignored.

They also will accosionally use the secretary of the Hunter Committee as an informal source and will ask Fairweather what to do for requests from their U.K. operations. The deliberations they hold on additives will consider available toxicology, molecular analogs, for example, and what happens on pyrolysis, and thus retain a fairly flexible position regarding any additive (this is similar to the system that we use). If these above considerations are acceptable to the panel, they will then give the green light to the overseas subsidiary requesting the service.

It must also be noted that each country which submits to the panel must accept responsibility for following the local applicable laws and regulations. In addition, local management can always override the committee recommendations but this would have to be done on the basis of business consideration in that area.

It might be mentioned that two of the members of the committee, usually scientists, are nominated as confidential recipients for information from the flavor houses. These recipients must not be involved in flavor formulation activities, and will not divulge the actual information to the committee, but will deliver the opinion which the committee will hand out.

There is one additional guiding principle in that occasionally questions are asked concerning the extent to which they consider the use of additives by competitors.

It may be of interest to note that our materials evaluation committee acts very much like their materials guidance panel. The only difference being that our committee issues a list of desired recommended and non-recommended materials. This, I believe, the B.A.T. panel does not give.

In terms of the additives guidance panels of B.A.T. we at R&D have been dealing in somewhat similar manner in that we have formed a flavor evaluation committee under my chairmanship which deals with new flavor materials and usage of compounds generated here at R&D.

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